

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**TALECRIS BIOTHERAPEUTICS, INC.,**

**Plaintiff,**

**V.**

**BAXTER INTERNATIONAL INC., and  
BAXTER HEALTHCARE CORPORATION,**

**Defendants.**

**BAXTER HEALTHCARE CORPORATION**

**Counterclaimant,**

**v.**

**TALECRIS BIOTHERAPEUTICS, INC., and  
BAYER HEALTHCARE LLC.,**

**Counterdefendants.**

**C.A. No. 05-349-GMS**

### Demand for Jury Trial

**PLAINTIFF'S REPLY TO DEFENDANTS' AFFIRMATIVE DEFENSES  
AND COUNTERCLAIMS**

Plaintiff and Counterdefendant Talecris Biotherapeutics, Inc. (“Talecris”) and Counterdefendant Bayer Healthcare LLC (“Bayer”), through their undersigned counsel, as and for their Reply to the counterclaims of Defendant and Counterclaimant Baxter Healthcare Corporation (“Baxter HC”) allege as follows:

## REPLY TO BAXTER HC'S COUNTERCLAIMS

42. Upon information and belief, admitted that Baxter HC is a corporation organized and existing under the laws of the State of Delaware. Talecris and Bayer are without knowledge

or information sufficient to form a belief as to the truth of Baxter HC's remaining averments and therefore deny the same.

43. Admitted.

44. Admitted that Bayer is a limited liability company organized and existing under the laws of the State of Delaware. Except as expressly admitted, the averments of this paragraph are denied.

45. Admitted that defendant Baxter HC attempts to plead an action under the Patent Laws of the United States and that this court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338, 2201 and 2202. Except as expressly admitted, the averments of this paragraph are denied.

46. Admitted.

47. Admitted.

48. Denied.

49. Admitted that Bayer is part of a worldwide pharmaceutical company having different divisions, including a Biological Products division. Except as expressly admitted, the averments of this paragraph are denied.

50. Talecris and Bayer are without knowledge or information sufficient to form a belief as to the truth of Baxter HC's averments and therefore deny the same, except they admit that the product relevant to this action is Baxter HC's intravenous immune globulin product GAMMAGARD LIQUID.

51. Talecris and Bayer are without knowledge or information sufficient to form a belief as to the truth of Baxter HC's averments and therefore deny the same.

52. Talecris and Bayer are without knowledge or information sufficient to form a belief as to the truth of Baxter HC's averments and therefore deny the same.

53. Admitted that a controversy between Baxter HC and Talecris exists relating to Baxter's GAMMAGARD LIQUID product and the process by which it is made. Except as expressly admitted, the averments of this paragraph are denied.

54. Admitted that United States patent application serial number 08/532,211, which issued as U.S. Patent No. 6,686,191 ("the '191 patent"), was filed on or about September 22, 1995, and that the '191 patent issued on February 3, 2004 and was assigned to Bayer. Except as expressly admitted, the averments of this paragraph are denied.

55. Talecris and Bayer admit that in paragraph 41 of its Answer, Baxter HC and Baxter International, Inc. purport to assert an affirmative defense alleging that Talecris lacks standing to bring suit. Talecris and Bayer incorporate by reference as if fully set forth herein each of their replies to paragraphs 42–54.

56. Admitted that Talecris contends that Baxter HC and others infringe the '191 patent and, upon information and belief, that Baxter HC contends that it does not infringe any valid claim of the '191 patent. Admitted that Baxter HC contends that an actual controversy has arisen and now exists between Counterclaimant Baxter HC and Counterdefendants Talecris and Bayer with respect to Baxter HC's infringement of one or more claims of the '191 patent. Except as expressly admitted, the averments of this paragraph are denied.

57. Admitted that a judicial determination of the respective rights of Talecris, Baxter HC, and Baxter International Inc. with respect to infringement of the '191 patent pursuant to 28

U.S.C. §§ 2201 and 2202 is necessary and appropriate under the circumstances. Except as expressly admitted, the averments of this paragraph are denied.

58. Talecris and Bayer admit that in paragraph 41 of its Answer, Baxter HC and Baxter International, Inc. purport to assert an affirmative defense alleging that Talecris lacks standing to bring suit. Talecris and Bayer incorporate by reference as if fully set forth herein each of their replies to paragraphs 42–54.

59. Admitted that Talecris contends that the ‘191 patent is valid and, upon information and belief, that Baxter HC contends that the ‘191 patent is invalid. Admitted that Baxter HC contends that an actual controversy has arisen and now exists between Counterclaimant Baxter HC and Counterdefendants Talecris and Bayer with respect to validity of the ‘191 patent. Except as expressly admitted, Talecris and Bayer deny the averments of this paragraph.

60. Admitted that a judicial determination of the respective rights of Talecris, Baxter HC, and Baxter International Inc. with respect to the validity of the ‘191 patent is necessary and appropriate under the circumstances. Except as expressly admitted, the averments of this paragraph are denied.

#### **REPLY TO BAXTER HC’S PRAYER FOR RELIEF**

Talecris and Bayer deny that Baxter is entitled to any relief whatsoever, including the relief that Baxter HC requests in its counterclaims.

#### **FIRST AFFIRMATIVE DEFENSE**

1. Baxter’s Counterclaim fails to state a claim upon which relief can be granted.

**SECOND AFFIRMATIVE DEFENSE**

2. Talecris repeats and realleges the allegations of the Complaint. The claims of the '191 patent are valid and enforceable in all respects, and infringed by Baxter.

**TALECRIS' AND BAYER'S PRAYER FOR RELIEF**

**WHEREFORE**, Talecris and Bayer request that this Court enter judgment in favor of Talecris and against Baxter as follows:

1. A declaratory judgment that Baxter International Inc.'s and Baxter Healthcare Corporation's GAMMAGARD LIQUID Immune Globulin Intravenous (Human) is made according to the processes claimed in the '191 patent, and that its importation into the United States and/or its offer for sale, sale, and/or use in the United States is, or will imminently constitute, an infringement, literally or under the doctrine of equivalents, of one or more claims of the '191 patent;

2. A judgment permanently enjoining Baxter International Inc. and Baxter Healthcare Corporation from making, using, selling, offering to sell, and importing into the United States GAMMAGARD LIQUID Immune Globulin Intravenous (Human) prior to the expiration date of the '191 patent;

3. A judgment permanently enjoining Baxter International Inc. and Baxter Healthcare Corporation from inducing infringement of the '191 patent prior to the expiration date of the '191 patent;

4. A judgment permanently dismissing with prejudice all counterclaims of Baxter Healthcare Corporation;

5. Attorneys' fees in this action under 35 U.S.C. § 285;

6. Costs and expenses in this action; and
7. Such further and other relief as this Court may deem just and proper.

*Of Counsel for Counterclaim  
Defendant Bayer Healthcare LLC*

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DATED: September 20, 2005

Respectfully submitted,  
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By: /s/ Jeffrey B. Bove

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**CERTIFICATE OF SERVICE**

I hereby certify that on September 20, 2005, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

Philip A. Rovner, Esquire  
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I hereby certify that on September 20, 2005, I caused to be served true and correct copies of the foregoing document on the following in the manner indicated below:

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